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Office of Regulatory Policy  
HFD - 7  
5600 Fishers Lane (Rockwall II Rm. 1101)  
Rockville, MD 20857

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,795,911. The application was filed on December 6, 2006, under 35 U.S.C. § 156. It is noted that applicant also filed an application for patent term extension for NDA 21-902 in U.S. Patent No. 5,968,973 (FDA Docket No. 2007E-0144), pursuant to 37 CFR 1.785.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Raul Tamayo at (571) 272-7728 (telephone) or (571) 273-7728 (facsimile).

Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Richard S. Barth, Esq.  
Frishauf, Holtz, Goodman & Chick, P.C.  
220 Fifth Avenue, 16th Fl.  
New York, NY 10001-7708

RE: VEREGENT<sup>TM</sup>, also known as POLYPHENON<sup>®</sup> E, (kunecatechins) Ointment, 15%  
FDA Docket No. 2007E-0176